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EXAMINER	
LUM, LEON YUN BON	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,409	LALEV ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 29-52* is/are pending in the application.

4a) Of the above claim(s) *29-31,36,41-44 and 47-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26,32,34-40,45 and 46* is/are rejected.

7)☒ Claim(s) *33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 1-26, 29-42 and 45-49) and species A1 (claims 22-26), B1 (claim 35) and C1 (claim 39) in the reply filed on May 6, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In light of the election, claims 29-31, 36, 41-44 and 47-52 are withdrawn. Claims 1-26, 32-35, 37-40 and 45-46 are examined on the merits.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

The specification fails to provide antecedent basis for the claimed "removal in step (e) is performed by addition of the same antibody," as recited in claim 12. Appropriate correction is required.

The specification fails to provide antecedent basis for cross-linking the second ligand to the affinity matrix after separating the second ligand from the first ligand and before mixing the second ligand with a cellular lysate, as recited in claim 33. Although cross-linking is described in the specification, see Specification, p.20 (first paragraph), it does not specifically describe or suggest performing this step after the ligand separation

and prior to mixing the immobilized second ligand with the cellular lysate. Appropriate correction is required.

The specification fails to provide antecedent basis for the limitations in claim 37. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 34-35, 37-38 and 45-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the phrase "the removal in step (e) is performed by addition of the same antibody." It is unclear how adding the same antibody as the immobilized antibody would constitute the removal process. Is the antibody attached to an isolatable means, e.g., magnetic bead, that allows it to remove unbound substances? If the antibody is simply added without a means of isolation, it is unclear how the unbound substances, once bound to the antibody, would be removed. Moreover, the added antibody would compete with the immobilized antibody for the second ligand and remove the ligand from the solid support, therefore doing more than simply removing unbound substances as claimed. Accordingly, the metes and bounds of the claim are unclear. Furthermore, the specification does not mention or suggest the removal

process and therefore does not provide clarity on this matter. For these reasons, claim 12 is vague and indefinite for failing to particularly point out and distinctly claim a removal step that utilizes the same antibody that is placed on a solid support in the immobilizing step.

Claim 34 recites the phrase “and wherein the change of the concentration of the checmial or biomolecule is below 30 mM.” Because this phrase is located after the second “and/or” term, it is unclear whether this phrase qualifies all phrases or just the phrase in between the two "and/or" terms. For purposes of prior art, the phrase in question is interpreted to qualify just the phrase in between the two “and/or” terms.

Claims 35 and 37-38 are dependent on claim 34 and vague and indefinite for the foregoing reason.

Claim 38 recites the limitation "the mutated protein" in lines 4 and 6 and the limitation "the mutation" in line 5. There is insufficient antecedent basis for this limitation in the claim. Indeed, base claims 1 and 34 do not mention a mutation or a mutated protein. It appears that the claim should instead be dependent on claim 35, which does recite a mutation.

Claim 45 recites a “protein-protein association.” Base claim 1, however, does not describe a protein, much less a protein-protein association or interaction. It is therefore

unclear what the relationship is between the method of claim 1 and the protein-protein association of claim 45. Accordingly, claim 45 is vague and indefinite.

Claim 46 is dependent on claim 45 and vague and indefinite for the foregoing reason.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 32, 37 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2004/0142488 to Gierde *et al.* ("Gierde") in view of U.S. Patent Application Publication No. 2004/0110675 to Sheehan.

i. Independent claim 1 is obvious

Gierde describes a method for performing affinity chromatography, in which an affinity molecule fixed on a column captures a biomolecule. '488 Patent, paras.0083-0092. The biomolecule can be a multi-protein complex. *Id.* (Table 1). With this description, Gierde teaches steps (a)-(b). Gierde also teaches step (c) by describing a wash step. *Id.* at para.0137.

Gierde does not, however, teach first and second ligands that associate through electrostatic forces or a step of separating the first and second ligands by decreasing the electrostatic force between them.

Sheehan describes heparin-protein interactions as being dominated by electrostatic forces, but can be disrupted by a NaCl gradient elution in an affinity column. '675 Pub., para.0189. Performing an elution assay in this manner is useful for investigating heparin binding to mutant proteins. *Id.*

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Gierde's method to investigate heparin-protein interactions using the affinity chromatography assay. By combining Gierde and Sheehan, Gierde's

method would be modified to include a NaCl elution step on a heparin-protein complex – i.e., heparin is the second ligand and the other protein is the first ligand. In this manner, the NaCl elution would separate the protein from the immobilized heparin. The skilled artisan would have been motivated to make the modification because Sheehan teaches that heparin-protein interactions are useful to investigate the heparin binding to mutant proteins. Moreover, because Sheehan describes the NaCl elution process in terms of an affinity separation step, the skilled artisan would have had a reasonable expectation of success in combining Sheehan's technique with the affinity chromatography method of Gierde.

ii. Dependent claims 32, 37 and 39-40 are obvious

Claims 32, 37 and 39-40 are dependent on claim 1 and taught by the prior art, as described below.

Regarding claim 32, Gierde describes the step of repeating the assay with cell lysates. '488 Patent at paras.0138, 0155.

Regarding claim 37, the NaCl acts as a competitor for heparin, as evidenced by Gierde and U.S. Patent Application Pub. 2003/0229212 to Fahrner *et al.* ("Fahrner"). Gierde indicates that in ion-exchange chromatography, an anlyate can be eluted by displacement using a salt. '488 Patent at para.022. Fahrner describes an ion-exchange chromatography as a competition between an ion and a substrate for a molecule of interest. '212 Patent, para.0008. Here, NaCl is used as an elution medium against heparin and another protein. *See supra* rejection of claim 1. In light of Gierde

and Fahrner, the NaCl competes with the complex to elute heparin or the protein, thereby binding to one of the proteins and meeting the claimed limitation.

Regarding claims 39-40, Gierde describes enzyme and polypeptide interactions. '488 Patent at para.0091.

Claims 1-11, 14-16, 18-19, 22-23, 34-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rigaut *et al.*, Nature Biotechnology (1999) 17:1030-1032 ("Rigaut"), cited in the IDS filed May 30, 2006, in view of Sheehan.

i. Independent claims 1-4 are obvious

Rigaut describes a tandem affinity purification method comprising the following steps: (1) fusing DNA encoding a TAP tag to DNA encoding a target protein, thereby creating a construct; (2) introducing the construct into a host cell or organism; (3) expressing the TAP-tagged target protein; (4) preparing an extract with the TAP-tagged target protein (corresponding to the claimed "second ligand"); and (5) performing a two-step affinity purification process in which (i) the TAP-tagged target protein is bound to a first affinity column through a first tag, (ii) the target protein is then cleaved from the first tag and bound to a second affinity column through a second tag, and (iii) the target protein is then eluted from the second column; wherein a wash step is performed after during each of the separation steps to remove contaminants. Rigaut, p.1030 (entire page). The target protein prior to the affinity separation steps can be bound to another protein (corresponding to the claimed "first ligand"). *Id.* (Figure 1, depicting the target protein attached to "associated proteins"). The TAP-tagged protein and other protein

come into contact *in vivo*, prior to the extraction step. *Id.* (describing the tandem affinity purification method as a useful tool to investigate protein complexes). Accordingly, the TAP-tagged protein "associates *in vivo*" with the other protein as claimed.

With the above description, Rigaut teaches steps (a)-(c) of claim 1, steps (a)-(e) of claim 2 and steps (a)-(h) of claim 3. Moreover, regarding claim 4 and the claimed "fusion protein complex comprising two or more subunits of which are fused to different affinity tags that can selectively bind to different affinity matrixes," this limitation is interpreted to include multiple proteins since the second ligand is defined in the claims as a protein complex. Rigaut indicates that the two tags can be placed on different proteins in a complex. *Id.* at p.1031 (right column, second paragraph). Accordingly, Rigaut teaches steps (a)-(h) of claim 4.

Rigaut does not, however, teach first and second ligands that associate through electrostatic forces or a step of separating the first and second ligands by decreasing the electrostatic force between them (i.e., step (d) of claim 1, step (e) of claim 2, step (i) of claim 3 and step (i) of claim 4).

Sheehan describes heparin-protein interactions as being dominated by electrostatic forces, but can be disrupted by a NaCl gradient elution in an affinity column. '675 Pub., para.0189. Performing an elution assay in this manner is useful for investigating heparin binding to mutant proteins. *Id.*

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Rigaut's method to investigate heparin-protein interactions using the tandem affinity purification assay. By combining Rigaut and Sheehan,

Rigaut's method would be modified to include a NaCl elution step on a heparin-protein complex – i.e., heparin is the second ligand and the other protein is the first ligand. In this manner, the NaCl elution would separate the protein from the immobilized heparin. The skilled artisan would have been motivated to make the modification because Sheehan teaches that heparin-protein interactions are useful to investigate the heparin binding to mutant proteins. Moreover, because Sheehan describes the NaCl elution process in terms of an affinity separation step, the skilled artisan would have had a reasonable expectation of success in combining Sheehan's technique with the tandem affinity separation method of Rigaut.

ii. Dependent claims 5-11, 14-16, 18-19, 22-23, 34-35 and 38 are obvious

Claims 5-11, 14-16, 18-19, 22-23, 34-35 and 38 are dependent on claims 1, 2 or 3 and obvious over the prior art for the following reasons.

With respect to claims 5-7 and 14-15, the TAP tag comprises Protein A that can bind to IgG. Rigaut at p.1030.

With respect to claims 8-9 and 18-19, the TAP tag comprises calmodulin binding peptide, which can be separated from the protein via EGTA. *Id.*

With respect to claims 10-11 and 16, TEV protease is used to cleave the TAP-tagged protein from the first affinity separation column. *Id.*

With respect to claims 22 and 23, the NaCl gradient incorporates an increasing ionic strength gradient, especially since the objective is to separate heparin from the other protein. *See supra* rejection of claim 1.

With respect to claim 34, NaCl is capable of separating heparin from the other protein, thereby having "capability" to separate the "first ligand from the second ligand," as claimed. *Id.*

With respect to claim 35, Sheehan describes a mutant protein. '675 Patent at para.0189 (describing heparin-protein binding using a column where the protein can be a mutant). Although heparin is attached to the column, *id.*, one of ordinary skill in the art would have found it obvious to try attaching the mutant protein to the column instead. As held by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (U.S. 2007), an obvious to try rationale is proper, given a "finite number of identified, predictable solutions." *KSR* at 1397. Indeed, the Court stated that in such a case, "a personal of ordinary skill has good reason to pursue the known options within his or her technical grasp." *Id.* Here, as would have been recognized by one of ordinary skill in the art, there are only two ways that the column can be used with a heparin-protein complex – either the heparin is bound to the column or the protein is bound to the column. Moreover, Sheehan indicates that the mutant protein can be recombinant. '675 Patent at para.0189. Accordingly, because Sheehan is combined with Rigaut, which teaches a recombinant method to produce a fusion protein, the skilled artisan would have recognized that Rigaut's method can be used to tag the recombinant mutant protein instead of heparin.

With respect to claim 38, one of ordinary skill in the art would have found it obvious to include an electrostatic charge identical to a mutation (species (b) in the claim) since the object of the combination of Riguat and Sheehan is to separate the

heparin and mutant protein. Moreover, because Rigaut teaches a gradient, *see supra* rejection of claim 1, the skilled artisan would have found it obvious to include the claimed electrostatic charge in the range of NaCl concentrations.

Claims 13, 17 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rigaut in view of Sheehan, as applied to claim 3 above, and further in of Gierde.

Rigaut and Sheehan do not teach the following limitations: step (g) as having an antibody-coated solid support (claim 13), the first affinity tag as calmodulin binding peptide (claim 17) or the second affinity tag containing one or more IgG binding regions of SpA-tag (claims 20-21).

Gierde describes a method of performing step elutions, in which sequential elutions are performed using different types of gradients. '488 Pub., paras.0181-0187. The gradients can be in any order and not required to be performed in a particular sequence. *See id.* (particularly paragraph 0185, describing a first elution by increasing ionic strength and a second elution by affinity binding, but not limited to these specific elution gradients).

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Rigaut and Sheehan's method by performing sequential elutions using ionic strength and affinity binding in that order. In making the combination, Rigaut and Sheehan's method of sequential Protein A and calmodulin binding peptide would be reversed – i.e., the first affinity separation would utilize

calmodulin binding peptide and the second affinity separation would utilize Protein A. Because Rigaut teaches a split TAP tag that places the two tags on different subunits, the skilled artisan would have recognized that Gierde's teaching of sequential elutions can be applied to bind the protein complex using the tags in any order. Accordingly, it would have been obvious to modify Rigaut and Sheehan's method using Gierde in the manner described. The skilled artisan would have made the modification because Rigaut indicates that TAP is an alternatively way of performing tandem affinity separation, *see supra* rejection of claim 4, and Gierde implies that two dimensional separations can be performed using a variety of elutions not in any particular order. Moreover, because all references are directed to affinity column separation, the skilled artisan would have had a reasonable expectation of success in combining the references.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rigaut in view of Sheehan, as applied to claims 1 and 22-23 above, and further in view of U.S. Patent No. 5,007,934 to Stone and U.S. Patent No. 5,849,885 to Nuyens *et al.* ("Nuyens").

Rigaut and Sheehan do not teach a KCl chemical agent.

Stone describes using NaCl or KCl as equivalent salts for removing glycoprotein or proteoglycan associated with collagen through electrostatic interaction. '934 Patent, col.7 ll.60-66.

Nuyens describes NaCl or KCl as equivalent salts for reducing electrostatic interactions between lactoferrin and other proteins. '885 Patent, col.4 ll.51-60.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Rigaut and Sheehan's method to use KCl as the eluting compound instead of NaCl. The skilled artisan would have performed the modification because it is well known in the art to use KCl as a substitute for NaCl for disrupting electrostatic interactions between proteins, as evidenced by Stone and Nuyens. For the same reason, the skilled artisan would have had a reasonable expectation of success in substituting KCl for NaCl.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rigaut in view of Sheehan, as applied to claims 1 and 22-23 above.

Rigaut and Sheehan do not teach the claimed range of concentration change. However, because Sheehan describes a NaCl gradient, it would have been obvious to one of ordinary skill in the art to select a change in concentration using the ranges claimed. Indeed, the skilled artisan would have arrived at the claimed ranges based on the doctrine of routine optimization. In a case decided by the precursor to the Federal Circuit, the court stated that a claim is not allowable where the skilled artisan could have arrived at the claim through routine experimentation on the optimum or workable ranges of the claim. *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (stating "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.") In *Aller*, the claims were

directed to a process taught by the prior art, except for a specific temperature and acid concentration range. *Id.* The court held, however, that the claims were not patentable because the skilled artisan could have arrived at the claimed ranges through routine optimization. Similar to that case, Rigaut and Sheehan teach all the limitations of claims 25 and 26, except for a concentration range. However, Sheehan indicates that a gradient can be applied, thereby inherently teaching a change in NaCl concentration. Lacking evidence to the contrary, it would have been within the routine skill of the skilled artisan to optimize the concentration ranges of the NaCl elution compound to arrive at the claimed ranges.

Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rigaut in view of Sheehan as applied to claim 1 above, and further in view of U.S. Patent 6,610,508 to Hentze *et al.* ("Hentze").

Rigaut and Sheehan do not teach the step of identifying protein-protein association as a putative cause for Alzheimer's disease.

Clary describes receptor-ligand complexes as reversible electrostatic attractions. '225 Patent, col.10 ll.66-67; col.11 ll.1-11.

Hentze describes a step of identifying protein-protein interactions in order to detect disease states, including Alzheimer's disease. '508 Patent, col.1 ll.33-54; col.30 ll.58-62,

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Rigaut and Sheehan's method to include the step of

identifying protein-protein interactions for detecting Alzheimer's disease. The skilled artisan would have made the modification because detecting Alzheimer's disease informs a patient whether the disease state is present. Moreover, the skilled artisan would have had a reasonable expectation of success because protein-protein interaction is a type of ligand-receptor interaction, which is known to be a reversible electrostatic attraction. U.S. Patent No. 5,753,225 to Clary *et al.* ("Clary"). Hentze's technique would therefore fit well with Rigaut and Sheehan's method utilizing electrostatic interactions.

Allowable Subject Matter

Claim 12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 33 is objected to as being dependent upon rejected base claims 1 and 32, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-

2872. The examiner can normally be reached on Monday to Friday (8:30 am to 5:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon Y. Lum/
Examiner, Art Unit 1641

/Nelson Yang/
Primary Examiner, Art Unit 1641